REMARKS

In the present application, claims 2, 17-28, 30-32 and 36 are pending. Claims 20, 21, 24, 25, 27 and 28, have been canceled. Therefore, claims 2, 17-19, 22, 23, 26, 30-32 and 36 remaining at issue.

A. **Rejections under 35 U.S.C. 112**

Claims 22-25, 31 and 32 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed had possession of the claimed invention. Applicants have amended the remaining pending claims in question, which effectively overcome the rejections under §112. These amendments are supported by the specification, as it is noted that the disclosure is to inhibition of complement activation on page 4 of the instant specification. Concerning claim 31, support for the statement "have a sequence of 207 amino acids" can be found on page 15, paragraph 2 of the instant specification.

2. **Rejections under 35 U.S.C. 102(b)**

Claims 2, 17-21, 26-28, 31 and 36 stand rejected under 35 U.S.C. 102(b) as being anticipated by pir62 Accession No. S03013, evidenced by the Ripoche et al. reference. Claims 2, 17-21, 26-28, 31 and 36 are also rejected under 35 U.S.C. 102(b) as being anticipated by pir65 Accession No. S00254, evidenced by the Ripoche et al. reference. Finally, Claims 2, 17-21, 26-28, 31 and 36 stand rejected under 35 U.S.C. 102(b) as being anticipated by Ripoche et al. as evidenced by pir62 Accession No. S03013 and pir65 Accession No. S00254. In order for a reference to act as a §102 bar to patentability, the reference must teach each and every element of

the claimed invention. *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 771 (Fed. Cir. 1983). Without the required teaching of "each and every element" as set forth in the claims, it is improper to continue such rejections under §102(b). Ripoche et al. and pir62 Accession No. S03013 and pir65 Accession No. S00254 do not teach each and every element of the claimed invention, specifically as amended, and thus fails as an anticipatory reference.

Initially, Applicants note that claims 20, 21, 24, 25, 27 and 28 have been canceled. Therefore the rejection as to these claims is now moot.

Applicants respectfully traverse this rejection on the ground that the reference, Ripoche et al., and pir62 Accession No. S03013 and pir65 Accession No. S00254 does not teach, suggest, or disclose the invention recited in the amended claims. Applicants' claims are directed to a truncated recombinant factor H and, more particularly, complement control protein modules 1-4, 1-5 or 1-6 of complement factor H. This fact is now emphasized in amended claims 17, 22 and 36, which include the term "consisting of" rather than "comprising."

By contrast, the reference teaches the entire sequence of human complement factor H and compares the human sequence to corresponding regions of mouse factor H cDNA. The reference explains that human factor H isolated from "outdated plasma" lacks two residues (Lys-Arg) from the C-terminus of the sequence. (Page 598, last paragraph, to page 599.) Though brief, this explanation of why a mere two amino acids may be missing from a sequence of 1,213 amino acids underscores the focus of this reference as being on the "entire" factor H sequence as a contiguous unit -- and not on discrete constituents.

Moreover, in the amino acid sequence disclosed in Figure 3, there is no indication of

which amino acids correspond to complement control protein modules or even what those protein modules may be. Nor is there any indication of where one complement control protein module ends and the next begins. In fact, nowhere in the reference is there any disclosure concerning complement control protein modules -- in this case, modules 1-4, 1-5 or 1-6 – as having complement inhibiting activity, apart from the rest of the sequence. Nor does the reference disclose constructs having CCP modules of complement factor H. Finally, and according to the specification at page 4, and Figure 4, it is the truncated recombinant factor H expressed in yeast of Applicant's invention that is approximately 10-100 fold more potent than the serum protein FHp155, and that the potency is to be found particularly in constructs representing complement control protein modules 1-6, 1-5 and 1-4. As stated, these claimed molecules of Applicant's invention are not disclosed in the reference, and thus the enhanced potency would not be an inherent property of the referenced compound. Therefore, Ripoche et al., and pir62 Accession No. S03013 and pir65 Accession No. S00254 evidenced from Ripoche et al., fail as anticipatory references. Applicants respectfully request that the rejection under §102(b) be withdrawn with respect to these claims.

CONCLUSION

Applicants respectfully submit that claims 2, 17-19, 22-23, 26, 30-32 and 36 are now in condition for allowance. The Commissioner is hereby authorized to charge any deficiency in fees to Deposit Account No. 23-0280.

Respectfully submitted,

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By: Monique A. Morneault

Monique A. Morneault, Reg. No. 37,893
Wallenstein Wagner & Rockey, Ltd.
311 South Wacker Drive, 53rd Floor
Chicago, Illinois 60606
Phone: (312) 554-3300
Attorneys for Applicants

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I hereby certify that this correspondence is, on the date shown below, being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to: Commissioner For Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on September 25, 2003.

Carolyn M. Vicino